9.4 510(k) Summary of Safety and Effectiveness

PreCision Dermatology, Incorporated
Precision Skin Emulsion
April 22, 2011

9.4.1 Sponsor Name

PreCision Dermatology, Incorporated
900 Highland Corporate Drive
Cumberland, RI 02864
Device Establishment Registration Number: 3005150234

Contact Individual:
Ronald M. Gurge, Ph.D.
Associate Director, Product Research & Development
PreCision Dermatology, Incorporated
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9.4.2 Device Name

Proprietary Name: Precision Skin Emulsion
Common/Usual Name: Wound Dressing

9.4.3 Identification of Predicate or Legally Marketed Device

Precision Skin Emulsion is substantially equivalent to the following predicate device:

Sinclair Skin Emulsion™ cleared under 510(k) K050158, from Sinclair Pharmaceuticals Limited. (Sinclair Skin Emulsion is currently marketed and distributed by Promius Pharma, LLC under the trade name Promiseb® Topical Cream.)

9.4.4 Device Description

Precision Skin Emulsion is a non-sterile, off-white, low odor, fragrance free, topical product. The Precision Skin Emulsion forms a physical barrier that helps to maintain a moist wound and skin environment. This is a prescription device.

9.4.5 Intended Use

Under the supervision of a healthcare professional, Precision Skin Emulsion is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Precision Skin Emulsion also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

9.4.6 Summary of Technological Characteristics of the Device Compared to the Predicate Devices

The proposed and referenced predicate devices both consist of humectant and emollient components in oil-in-water emulsion that are applied topically and rubbed on the affected skin to relieve the symptoms of seborrhea and seborrheic dermatitis and maintain a moist skin environment.

9.4.7 Tests and Conclusions

Precision Skin Emulsion contains identical components in similar quantities to those of the predicate device Sinclair Skin Emulsion. Both the predicate and proposed devices are in the form of an emulsion. Precision Skin Emulsion has the same intended use and technological characteristics as the predicate device. Therefore Precision Skin Emulsion is substantially equivalent to Sinclair Skin Emulsion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

PreCision Dermatology, Incorporated
% Ronald M. Gurge, Ph.D.
Associate Director, Product Research & Development
900 Highland Corporate Drive
Cumberland, Rhode Island 02864

DEC 1 3 2011

Re: K111168
Trade/Device Name: Precision Skin Emulsion
Regulation Number: Unclassified
Product Code: FRO
Dated: November 7, 2011
Received: November 8, 2011

Dear Dr. Gurge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.7 Statement of Indications for Use

510(k) Number (if known): K111168

Device Name: Precision Skin Emulsion

Indications For Use:

Under the supervision of a healthcare professional, Precision Skin Emulsion, is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Precision Skin Emulsion helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111168